K020466

MAY 0 8 2002

SUMMARY OF 510-K SAFETY AND EFFECTIVENESS

Topical Oxygen Oxygen chambers / Topical Oxygen Chambers for Extremities

EFFECTIVENESS PROBLEMS:

Topical oxygen oxygen has diminished or no effectiveness when treating:

1.) Ulcers / Wounds associated with the following:
- severe ischemic disease
- Raynaud's Disease
- Acute or chronic ischemic disease secondary to thrombosis, embolism
- Avascularity (absent blood supply)
- Osteomyelitis

2.) Ulcers / wounds that have not been adequately debrided of necrotic tissue. Dead tissue will not allow oxygen to penetrate and oxygenate the tissue.

3.) Ulcers / wounds that have not been irrigated clean of any topical ointments that may cause a barrier over the wound, preventing the penetration of oxygen into the viable tissue. [All wound dressings must be removed to expose tissue to oxygen]

SAFETY

Upon reviewing MDR, there are no reported adverse reactions to topical oxygen oxygen chambers. However, the following adverse safety concerns should be observed:

1.) Infection: Infection may result if the material used in the device or its contruction prevent proper disinfection.

2.) Fire: Pure oxygen required in oxygen chambers is highly combustible and hazardous when an open flame is present.

3.) Decrease in local tissue circulation:
Greater than 22 mmHg of continuous oxygen pressure in the chamber, may occlude arterial circulation, leading to a decrease in local tissue circulation.

Note: Our chamber requesting 510k clearance and the two predicate chambers mentioned in our premarket notification, provide up tp 50mmHg of pressure intermittently, cycling / ramping from 0 mmHg to 50 mmHg of pressure over a 15 to 20 second cycle *, then venting back to 0mmHg of pressure within 5 seconds. This cycling or intermittent compression will not have the same degree of safety Concern as a constant, non-intermittent pressure on the extremity. (See letter from Dr. Benjamin in section F:38* Cycle times may vary dependent on liter flow and the degree to which the the chamber volume is reduced by the limb, positioning pads, etc.

4.) Oxygen chambers that apply oxygen under positive intermittent (pulsed) pressure are contraindicated for use in the presence of acute thrombophlebitis, as the pressure variations may dislodge the thrombus.

5.) Allergic reactions: Sleeve used to seal the extremity inside the chamber contains natural rubber latex which may cause allergic reaction.

Discussion of Pressures above 22 mmHg:

In the Federal Register notice dated January 19, 1982, volume 47, #12, page 2645, a statement is made addressing the possibility of occluding blood flow to tissues when pressures exceed 22 mmHg. This may be a valid concern when it applies to the topical oxygen chambers that place the extremity inside of a plastic bag and inflate the bag with oxygen to a constant / continuous pressure of 22 mmHg for time periods of one hour or more. (i.e.- GWR- O2 Boot / Lifetech Systems- Lifetech Cassette / Oxycure –Boot)

Metro Medicals chamber and the predicate devices cited in this submission by: Topox / Advanced Hyperbaric Technologies, Inc. and Stephenson Industries are also classified as topical oxygen chambers for extremities, however, there are some major differences in their design and operation which should be addressed as they relate to the safety concerns of chambers that exceed 22 mmHg.

The big difference is that the chambers provide intermittent pressure up to 50 mmHg and do not exceed 22 mmHg for more than 15 to 30 seconds before they vent to nearly 0mmHg.

In our chamber performance qualification testing (see actual data in section G) the HEC 1000 cycled from 0mmHg to 50mmHg with an average fill time of less than 25 seconds. Therefore, the amount of time that the unit is actually applying pressures above 22 mmHg would be no longer than 15 seconds before venting to nearly 0 mmHg for the next 3 to 4 seconds. The following cycle begins to pressurize and will exceed 22 mmHg in approximately 12 to 15 seconds before reaching the set pressure of 50mmHg under 25 seconds. (See letter from Dr. Benjamin in section F regarding his experiences using the intermittent chambers on over 400 patients.)

In summary, the chamber will apply pressures above 22mmHg for approximately 15 seconds and pressures less than 22 mmHg for approximately 15 seconds. The safety risk of capillary occlusion is minimized by limiting the length of time to no more than 15 seconds above 22 mmHg and allowing approximately 15 seconds for capillary refill to take place. There is a much greater risk of reducing blood flow to the tissues when a constant pressure is applied. Even if the unit failed to reach its set maximum pressure of 50mmHg, the software would automatically vent the chamber and remain on hold, if the set pressure was not achieved within 60 seconds. Assuming that the unit would reach 22 mmHg within approximately 15 seconds, the worst case scenario would be that the extremity would be under pressures greater than 22 mmHg for no greater than 45 seconds then vent and hold at nearly 0 mmHg until the continue screen was pressed. In addition, the unit is designed with a pressure relief valve to vent automatically upon reaching 50 mmHg of pressure. This built in redundancy of the 60 second timer and pressure relief valve addresses any safety concerns of exceeding prolonged constant pressures above 22 mmHg. A review of MDR and MAUDE data bases turns up no reported claims of adverse reactions resulting from topical oxygen chambers for extremities.

CITATIONS / SEARCH METHODOLOGY AND REFERENCES FOR SAFETY AND EFFECTIVENESSS STATEMENTS:

1.) Search of MDR and MAUDE databases for reports on any adverse reports relating to topical oxygen oxygen chambers.

2.) Code of Federal Regulations pertaining to the classification of topical oxygen chambers for extremities. (21 CFR 878.5650)

3.) Fisher, Boguslav. Treatment of Ulcers on the legs with Hyperbaric Oxygen. Journal of Dermatologic Surgury, Inc. 1975; 3:55-58

4.) Heng, MCY: Topical Oxygen Therapy for Problem Skin Wounds. Dermatol Surgury Oncology 19:784-793, 1993

5.) Lehman WL, Jones WW, Allo MD, Johnston RM. Human Bite Infections of the Hand: Adjunct treatment with Hyperbaric Oxygen. Infections in Surgery 1985; 460-465.

6.) Williams RL, Hyperbaric Oxygen Therapy and the Diabetic Foot. Journal of American Podiatric Medical Association.1997; 279-291.

7.) Heng MCY, Harker J, Bardakjian VB, Ayvazian H, Enhanced Healing and Cost Effectiveness of Low Pressure Oxygen Therapy in Healing Necrotic Wounds. Ostomy Wound Management 2000; 46(3): 52-62

8.) Rossi F, Elsinger E, Topical Hyperbaric Oxygen Therapy for Lower-Extremity Wound Care: An Overview. Podiatry Management, November 1997; 110-111

9.) Diamond E, Forst MB, Hyman SA, Rand SA, The Effect of Hyperbaric Oxygen on Lower Extremity Ulcerations. Journal of he American Podiatry Association, Volume 72, Number 4, April 1972; 180-184

10.) Rehm KB, Goudberg D, Longobardi J, Tidwell G, THBO: Putting Pressure On Non–Healing Wounds. Podiatry Today, December 1997; 54,56,64,65

11.) Olejniczak S, Zielinski A, Eloise, Low Oxygen Therapy in Management of Leg Ulcers. Michigan Medicine, Volume 74, Number 32, November 1975; 707-712

12.) Benjamin RS, Letter Addressing Safety and Effectiveness Of THBO, November 29, 2001

13.) Hess R, Letter addressing safety and effectiveness of THBO, May 2, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 8 2002

Mr. Paul Mocur
President
Metro Medical Manufacturing, Inc.
12985 Wayne Road
Livonia, MI 48150

Re: K020466
Trade/Device Name: Topical (O2) Oxygen Chamber for Extremities
Regulation Number: 878.5650
Regulation Name: Topical oxygen chamber for extremities
Regulatory Class: III
Product Code: KPJ
Dated: February 8, 2002
Received: February 12, 2002

Dear Mr. Mocur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(K) Number (if known): K020466 Page 1 of 1

Device Name: HEC 1000 [Topical Oxygen Chamber for Extremities]

Indications For Use:

" STATEMENT OF INDICATIONS FOR USE "

- Burns
- Post Surgical Infections
- Venous Stasis Ulcers
- Diabetic Ulcers
- Frostbite
- Amputations / Infected Stumps
- Skin Grafts

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020466